RAPID Cures Act
Bill Summary

The Rapid Pathogen Identification to the Delivery of Cures Act, or RAPID Cures Act, develops a strategy to achieve a dramatic reduction in the timeframe required for the delivery of drugs and vaccines to counter pathogen threats for which we have no existing countermeasures. The institution of a national rapid response "Bug-to-Drug" capability will be a significant boost to our biodefenses against the emerging and future threat of bioengineered biological weapons, as well as naturally occurring novel threats, such as SARS or pandemic flu.

In addition to improving antimicrobial and vaccine development capabilities, an area currently neglected by the private sector, the technical spin-offs of such an endeavor are also likely to benefit the domestic pharmaceutical and biotechnology industries more generally, and public health more broadly. Long timeframes and high failure rates typical of drug development processes are a significant cause of high R&D costs, and thus high prescription drug costs. Neither the basic or applied research necessary to solve persistent bottlenecks in development, nor a significant free-market or coordinated government effort, exists to address these shortcomings.

Section 2. Findings and Policy
Lays out the justification for this bill and provides an explicit policy declaration of Congress to make the intent clear. The report accompanying this bill, *Beyond Anthrax: Confronting the Future Biological Weapons Threat* lays out the case in greater detail.

Section 3. Rapid Biodefense Countermeasures Development National Strategy
Amends the Homeland Security Act to define the elements of the strategy required to be developed. It directs the strategy to be produced jointly by the Secretaries of Homeland Security, Health and Human Services, and Defense. It includes a call for a survey of the challenges to shortening the Bug-to-Drug development time and the development of a comprehensive national research plan to address these challenges. It also requires specific issue and focus areas that must be considered in developing the strategy.

Significant input from academia and the private sector is required, lying outside any single agency's mission, programmatic responsibilities and expertise. Therefore, the executive branch is given explicit authority to contract with private firms and/or academic groups to conduct portions of this analysis.

Section 4. Clinical Research Under Emergency Conditions
Directs the Secretary of Health and Human Services to establish a system for the rapid development of clinical trial protocols during a crisis, and for the dissemination of results and recommendations to clinicians nationwide. A reserve emergency fund to help run these trials is authorized.

Section 5. Interagency Working Group
Updates the Bioterrorism Act of 2002, which establishes an interagency working group to manage various biodefense issues that cut across agencies to include the Department of Homeland Security and to include in the working group tasks the development of the strategy.

Section 6. Developing the Capability for Rapid Biodefense Countermeasure Development
Amends the Public Health Service Act, the Homeland Security Act, and the Defense Authorization Act for 2004 to authorize research and development activities at HHS, DHS, and DOD to be conducted to help achieve the policy goal of the Act.